

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Wai et al.	
Patent No.:	7,517,532	Art Unit: 1624
Issue Date:	April 14, 2009	
Serial No.:	10/526,275	Examiner:
Docket No.:	21162YP	Murray, Jeffrey H.
Filed:	March 1, 2005	
For:	DIHYDROXYPYRIDOPYRAZINE-1,6-DIONE COMPOUNDS USEFUL AS HIV INTEGRASE INHIBITORS	Confirmation No. 8334

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

LETTER – CORRECTION OF ERRORS AND AN OMISSION IN A REQUEST FOR
RECONSIDERATION OF AN APPLICATION FOR PATENT TERM ADJUSTMENT

Sir:

A request for reconsideration ("Request") was electronically filed on February 3, 2010. Its identification number is EFS ID No. 6937958. The Request seeks reconsideration of the USPTO decision dated December 15, 2009 ("Decision") dismissing the application for patent term adjustment ("PTA Application") filed April 17, 2010 for US 7,517,532. Subsequent to the filing, the following errors and omission were discovered with respect to the enclosure and exhibits accompanying the Request:

- a. The Request stated that Form PTO/SB/131 was enclosed, but the form was incorrectly labeled Exhibit One. PTO/SB/13 should be identified as a separate document with the Doc Code: 21162YP_PET.PTA.RCAL_3FEBRUARY2010.
- b. The Request stated that the Decision was attached as Exhibit One, but was incorrectly labeled as Exhibit Two. The Decision should be labeled Exhibit One.
- c. The Request stated that the PTA Application was attached as Exhibit two, but was inadvertently omitted from the filing. The PTA Application is enclosed herewith and is labeled Exhibit Two.

It is requested that this letter be joined with the Request and that the corrections to the Request set forth in a, b and c above be incorporated into the Request.

No fee is believed to be due as a result of the submission of this letter. However, if a fee is due, the Commissioner is authorized to charge the fee to Deposit Account No. 13-2755.

Respectfully submitted,
By: /Kenneth R. Walton, Reg. No. 32,951/
Kenneth R. Walton, Reg. No. 32,951
Attorney for Patentees
MERCK & CO., Inc.
P.O. Box 2000
Rahway, New Jersey 07065-0907
Tel.: (732) 594-3462

Date: February 4, 2010

Attachment (Exhibit 2)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wai et al.	Art Unit: 1624
Patent No.: 7,517,532	Examiner:
Issue Date: April 14, 2009	Murray, Jeffrey H.
Serial No.: 10/526,275	Confirmation No.
Docket No.: 21162YP	8334
Filed: March 1, 2005	
For: DIHYDROXYPYRIDOPYRAZINE-1,6-DIONE	
COMPOUNDS USEFUL AS HIV INTEGRASE	
INHIBITORS	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(b)

Sir:

This is a request for reconsideration of the patent term adjustment (PTA) indicated in the Issue Notification mailed March 25, 2009 and in U.S. Patent No. 7,517,532 issued April 14, 2009 ("Patent").

Background

An application for PTA was filed November 7, 2008 at the time of submission of the issue fee payment. The application requested reconsideration of the PTA as it related to the Patent Office's failure to issue the patent within three years of the filing date of the application. In a decision of the Office of Petitions mailed March 16, 2009 ("Decision"), the application for PTA was held in abeyance. Applicants were given two (2) months from the issue date of the patent (i.e., until June 14, 2009) to file a written request for reconsideration of the application for PTA. The Decision stated that all requirements of 37 CFR 1.705(d) must be met in the request for reconsideration, except that no additional fee is due. A copy of the Decision is attached hereto as Exhibit 1.

Request for Reconsideration

In accordance with the Decision, it is requested that the PTA determination be corrected to include the days accrued pursuant to 37 CFR 1.702(b) for failure to issue the patent within three years of the actual filing date of the application. The title page of the Patent discloses a PTA determination of 630 days. Applicants' position is that this determination is incorrect, because it

does not account for delay accrued under 37 CFR 1.702(b) and that the correct PTA determination is 1001 days.

Details

According to 37 CFR 1.702(a)(1), the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. 371 in an international application. The requirements under section 371 for this international application were fulfilled on March 1, 2005. The date fourteen months after the section 371 requirements were fulfilled is May 1, 2006. A first office action was mailed on December 14, 2007, which constitutes 592 days of Patent Office delay under 37 CFR 1.703(a)(1); i.e., the number of days from May 1, 2006 to December 14, 2007.

According to 37 CFR 1.702(a)(4), the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent not later than four months after the date on which the issue fee was paid. The issue fee for the subject application was paid November 7, 2008. The date four months after the issue fee payment is March 7, 2009. The patent issued on April 14, 2009, which is 38 days of Patent Office delay under 37 CFR 1.703(a)(6); i.e., the number of days from March 7, 2009 to April 14, 2009.

There is no overlap in the 592 days of delay under 37 CFR 1.703(a)(1) and the 38 days under 37 CFR 1.703(a)(4). Accordingly, the total delay under 37 CFR 1.703(a) is $592 + 38 = 630$ days.

There were no circumstances constituting a failure of Applicants to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 CFR 1.704. Accordingly, the PTA accrued under 37 CFR 1.703(a)(1) and (a)(4) = PTO Delay – Applicant Delay = $630 - 0 = 630$ days.

According to 37 CFR 1.702(b), the term of the original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the national stage commenced under 35 U.S.C. 371. The date three years after commencement of the national stage is March 1, 2008. The date the patent issued is April 14, 2009. According to 37 CFR 1.703(b), the number of days accrued under Rule 1.702(b) is 409 days; i.e., the number of days from March 1, 2008 to April 14, 2009.

There was no delay due to Applicants during the 1.703(b) period.

Under 37 CFR 1.703(f), any days of delay for Patent Office issuance of the patent more than three years after the filing date of the application which overlap with the days of PTA accorded prior to issuance of the patent will not result in any additional PTA. The 409 days of Patent Office delay under 37 CFR 1.703(b) actually overlaps with the 38 days of Patent Office Delay under 37 CFR 1.703(a)(4).

There is no actual overlap between the delay under 37 CFR 1.703(a)(1) and 37 CFR 1.703(b); i.e., the delay under 1.703(a)(1) ended on December 14, 2007 and the delay under 1.703(b) began to accrue on March 1, 2008.

Accordingly, the PTA is 592 days (1.703(a)(1) delay) + 38 days (1.703(a)(4) delay) + 409 days (1.703(b) delay) – 38 days (overlap) – 0 (Applicant delay) = 1001 days.

The PTA determination of the Patent Office (copy attached hereto as Exhibit 2) lists 630 days of Patent Office delay and 0 days of Applicant delay. The Patent Office PTA determination does not include the delay due to the failure to issue the patent within three years of the commencement of the national stage. The rationale for this omission is that the Patent Office has considered the delay under 37 CFR 1.702(a)(1)&(a)(4) to be overlapping with delay under 1.702(b) such that an applicant is entitled to the delay due to either 1.702(a)(1)&(a)(4) or 1.702(b), whichever is longer, but not both. Reference is made, however, to Wyeth v. Dudas, Civil Action No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063 (DC, September 30, 2008) ("Wyeth"; copy attached hereto as Exhibit 3). The Wyeth case presents essentially the same factual situation as presented in the instant application. In Wyeth, the plaintiff argued that the time period due to actual Patent Office delay and the time period due to failure of the Office to issue the patent within 3 years of the filing date do not overlap unless there is actual overlap. The Court agreed, stating that, for purposes of determining PTA, the "only way that periods of time can 'overlap' is if they occur on the same day." Applying the Wyeth precedent to the instant situation, there is actual overlap between only the 38 days of Patent Office Delay under 1.703(a)(4) and the 409 days of Patent Office Delay under 1.702(b). Accordingly, Applicants are entitled to the sum of all of the days of delay less 38 days, which is 1001 days as calculated above.

It is further noted that the patent that issues from the subject application will not be subject to a terminal disclaimer.

Accordingly, it is requested that the PTA determination for this application be changed to 1001 days.

Respectfully submitted,
By: /Kenneth R. Walton, Reg. No. 32,951/
Kenneth R. Walton, Reg. No. 32,951
Attorney for Applicants
MERCK & CO., Inc.
P.O. Box 2000
Rahway, New Jersey 07065-0907
Tel.: (732) 594-3462

Date: April 17, 2009